DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 2910949

September 19, 2000

Mr. Gary Brainin, President
Mr. Thomas Morthorst, Vice-President
Altair Corporation
350 Barclay Boulevard
Lincolnshire, Illinois 60069-3643

WARNING LETTER

Dear Messrs. Brainin and Morthorst:

An inspection of your medicated feed manufacturing facility Kern Livestock Supplement Co., Inc., located at 130 Industrial Street, Bakersfield, California, 93387, on August 22 and 23, 2000, by Food and Drug Administration (FDA) Investigator John A. Gonzalez revealed significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21 Code of Federal Regulations (CFR), Part 225). Such deviations cause the medicated feeds manufactured at your mill to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act. The following deviations were observed:

Our investigation found failure to flush or otherwise clean mixing equipment between batches of feeds medicated with active drug ingredients; failure to maintain complete master record files; failure to review label stock periodically and discard discontinued labels; failure to separate maintenance and storage areas; and failure to identify the correct lot numbers of drugs on your daily drug inventory records.

Causing the adulteration of drugs after receipt in interstate commerce, and delivering for introduction into interstate commerce of any article in violation of Section 501 or 502, are violations of Section 301(k) of the Act.

The above is not intended as an all-inclusive list of CGMP violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring

that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these CGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill License under Section 512(m)(4)(B)(ii) of the Act and Title 21, Code of Federal Regulations, Part 514.115(c)(2). (This letter constitutes official notification under the law.) Based on the results of the August 22 and 23, 2000, inspection, evaluated together with the evidence before FDA when the Medicated Feed Mill License was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

Within fifteen days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to John A. Gonzalez, CSO, 2202 Monterey Avenue, Suite 104E, Fresno, California, 93721.

Sincerely yours,

Thomas H. Sidebottom

Thomas H. Sidebottom
Acting District Director
San Francisco District